

REMARKS

This Response is submitted in response to the Final Office Action mailed on December 30, 2002.

The Final Office Action rejects claims 1-19 under 35 U.S.C. §103 as being unpatentable over either U.S. Patent No. 5,948,430 ("*Zerbe*") or U.S. Patent No. 4,777,046 ("*Iwakura*") in view of U.S. Patent No. 5,433,960 ("*Meyers*"). Applicants respectfully submit that all of the above-mentioned rejections have been overcome or are improper for reasons set forth below.

The present invention provides a pullulan free edible film composition and methods for making the same. The pullulan free edible film composition comprises an effective amount of a film forming agent comprising carageenan, an effective amount of at least one bulk filler agent, and an effective amount of at least one plasticizing agent. Furthermore, the edible film of the present invention dissolves quickly in the mouth of the user. The invention also provides novel methods for using the edible film composition. Applicants respectfully submit that each of the cited references fails to teach or arguably suggest a number of the features of the claimed invention.

Zerbe primarily relates to a water-soluble film composition for oral administration which includes a water-soluble polymer or a combination of water-soluble polymers, one or more plasticizers or surfactants, one or more polyalcohols, and a pharmaceutically or cosmetically active ingredient. See Col. 2, lines 30-35. The film disclosed in *Zerbe* exhibits rapid dissolution/disintegration upon administration in the oral cavity. See Col. 2, lines 14-20 and Abstract. As admitted by the Examiner, there is no teaching or suggestion relating to a film-forming agent which includes carageenan, as is the case with the present invention. The above-mentioned feature is specifically claimed in all of the composition and method claims of the present invention.

Iwakura similarly fails to disclose or suggest all of the features of the claimed invention. Specifically, *Iwakura* discloses a sustained release preparation which preferably sticks in the user's mouth for "8 hours or more." See Col. 4, line 58 – Col. 5, line 8. This is clearly different from the presently claimed film compositions and methods which require that the film dissolve quickly in the oral cavity of the user. Thus, *Iwakura* clearly and unmistakably constitutes a

teaching away from the presently claimed invention. It is established law that an Examiner's proposed modification cannot change the principle of operation of a reference. See MPEP 2143.01. Finally, as admitted by the Examiner *Iwakura* does not teach using a film-forming agent which includes carrageenan. See OA at 4.

As discussed in detail above, *Zerbe* and *Iwakura* do not teach or suggest all of the claimed features of the present invention. Moreover, as set forth below *Meyers* does not remedy the deficiencies of either of these references.

At the outset, Applicants submit that *Iwakura* even if combinable would not render obvious the present invention. Notwithstanding this argument, it is clear that *Iwakura* cannot be combined with *Meyers* since this combination would clearly change the principle of operation of *Iwakura*. As set forth above, *Iwakura* teaches the desirability of a long lasting film, whereas the present invention claims a composition which dissolves quickly in the user's mouth. As such, it is clear if *Meyers* was combined with *Iwakura* it would frustrate the principle goal of *Iwakura* in order to teach the present invention. As such, Applicants submit this rejection is improper and request withdrawal of the same.

With regard to the combination of *Meyers* and *Zerbe*, *Meyers* primarily relates to coating a chewing gum composition with a film forming agent, one of which is carrageenan in order to increase moisture stability of the chewing gum composition. See Col. 3, lines 23-28. This is clearly different from making a quick dissolving edible film composition itself which includes carrageenan as one of several components and methods of using the same. As such, there is simply no motivation to combine these references. The mere fact that references are combinable does not render the combination obvious unless the prior art suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990) and MPEP 2143.01. Here, it is clear there is no such suggestion in *Meyers*.

Meyers also does not teach "film forming agents in combination with bulking agents and plasticizers." See OA at 4. As is apparent from Column 6, lines 25-35 of *Meyers*, each item in the recited list of components is being used individually not together. As such, the mere teaching of using a film forming agent such as carrageenan to coat a chewing gum would not motivate one skilled in the art to create a quick dissolving edible film composition including several

components, one of which is carrageenan, or any methods of using the same. Indeed by its very nature chewing gum compositions are necessarily designed to be long lasting which is the exact opposite of the presently claimed quick dissolving film. Applicants submit that insofar as *Meyers* relates to coating chewing gum it clearly constitutes non-analogous art, and thus is not properly combinable with the teachings of *Zerbe*. Accordingly, Applicants respectfully submit that this obviousness rejection with respect to claims 1-19 has been overcome and request withdrawal of the same.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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